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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/799,854	03/12/2004	Alexander P. Dorr	UCAL-296	2176

24353 7590 04/17/2007

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EXAMINER	
PARKIN, JEFFREY S	
ART UNIT	PAPER NUMBER
1648	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/17/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/799,854	DORR ET AL.	
	Examiner	Art Unit	
	Jeffrey S. Parkin, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *03* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 February 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above claim(s) *19-28* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12 March 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *07/08/04; 05/25/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Office Action

Status of the Claims

Claims 1-28 are pending in the instant application. Applicants' election with traverse of Group I (claims 1-18) in the communication filed 01 February, 2007, is acknowledged. The traversal is based upon the premise that it would not constitute an undue burden to examine all the groups concomitantly. This argument is not found to be persuasive for the reasons of record clearly set forth in the original restriction requirement. Moreover, there are two criteria for a proper requirement for restriction between patentably distinct inventions: (A) The inventions must be independent (see M.P.E.P. § 802.01, § 806.06, § 808.01) or distinct as claimed (see M.P.E.P. § 806.05-806.05(j)); and (B) There would be a serious burden on the examiner if restriction is not required (see M.P.E.P. § 803.02, § 808, and § 808.02). For purposes of the initial requirement, a serious burden on the examiner may be *prima facie* shown by appropriate explanation of separate classification, or separate status in the art, or a different field of search as defined in M.P.E.P. § 808.02. As set forth in the original restriction requirement, each of the identified groups has a separate classification and/or will necessitate different searches. Accordingly, **the requirement is still deemed to be proper and is therefore made FINAL.** Claims 19-28 are withdrawn from further consideration by the examiner, pursuant to 37 C.F.R. § 1.142(b), as being drawn to a non-elected invention.

37 C.F.R. § 1.98

The information disclosure statements file 08 July, 2004, and 25 May, 2006, have been placed in the application file and the information referred to therein has been considered.

Brief Description of Drawings

The specification is objected to because the brief description of the drawings is deficient. See M.P.E.P. § 608.01(f). The description of Figure 5 is deficient because it fails to clearly identify which amino acid sequence corresponds to which sequence identifier. For instance, which amino acid sequence (AAL29460, P04606, P04326, etc.) does SEQ ID NO.: 42 correspond to? Appropriate correction is required. Applicants may wish to amend the brief description of the figures to clearly set forth the corresponding sequences and their attendant SEQ ID NOS.: or this information may be incorporated into the figure itself.

35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 are rejected under 35 U.S.C. § 102(b) as being anticipated by Deng et al. (2000). Deng and colleagues provide isolated acetylated human immunodeficiency virus type 1 (HIV-1) Tat (Ac-Tat) polypeptides (e.g., see Figure 1). The authors noted that Tat is acetylated at Lys^{50} within the core sequence $^{49}RKKRRQ^{54}$. Thus, this teaching meets all of the claimed limitations.

Claims 1-3 are rejected under 35 U.S.C. § 102(a), or alternatively under 35 U.S.C. § 102(b) as being anticipated by Mujtaba et al. (2002).[1] Mujtaba and colleagues provide isolated acetylated human immunodeficiency virus type 1 (HIV-1) Tat polypeptides (e.g., see Figure 1B and Figure 3C). The authors noted that Tat is acetylated at Lys^{50} within the core sequence $^{49}RKKRRQ^{54}$. Thus, this teaching meets all of the claimed limitations.

35 U.S.C. § 103(a)

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to

[1] It is noted that applicants earliest claimed priority date is 19 March, 2003. The Mujtaba *et al.* (2002) publication has a March, 2002, publication date. However, at the time of this office action it was not readily manifest if the public availability date of this teaching was before or after March 19. Accordingly, a rejection has been made under both sections of the statute. When the Scientific and Technical Information Center (STIC) provides the examiner with the actual public availability date, it will be communicated to applicants.

> a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 U.S.P.Q. 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 4 and 5 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Deng *et al.* (2000) in view of Wildey *et al.* (1988). As previously set forth, Deng and colleagues provide acetylated HIV-1 Tat peptides. These peptides were acetylated at Lys^{50} and comprise the core sequence SYGRKKRRQ. This teaching does not disclose acetylated Tat peptides that contain a C-terminal cysteine residue. However, Wildey and associates unequivocally demonstrate that attaching a C-terminal cysteine residue to a polypeptide facilitates its conjugation to a carrier protein. Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to modify the polypeptides of Deng *et al.* (2000), to include a C-terminal cysteine residue, as taught by Wildey et al. (1988), since this would facilitate the conjugation of these peptides to a carrier protein. It would have also been *prima facie* obvious to use Ac-Tat polypeptides (SYGRKKRRQRC, SYGRKKRRQRRC, and SYGRKKRRQRRRC) up to and including the end of

the basic domain (aa 57) as targets for antibody generation since this is a hydrophilic region and it has been well-demonstrated that hydrophilicity correlates to immunogenicity.

Claims 6-18 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Deng *et al.* (2000) in view of Wildey *et al.* (1988) and Gu *et al.* (2002). The claims contain additional art-recognized limitations pertaining to the nature of the immunogenic composition (i.e., presence of a linker, carrier protein, adjuvant, etc.). The teachings of Deng *et al.* (2000) and Wildey *et al.* (1988) have already been set forth. Gu and colleagues provide immunogenic compositions comprising polypeptides linked to a carrier (e.g., tetanus toxoid) through a linker containing an adjuvant (e.g., ALUM) (see claims). Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to prepare immunogenic compositions, as taught by Gu *et al.* (2002), comprising the Ac-Tat polypeptides of Deng *et al.* (2000) and Wildey *et al.* (1988), since this would reasonably be expected to generate strong immune responses against Ac-Tat.

Claims 4 and 5 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Mujtaba *et al.* (2002) in view of Wildey *et al.* (1988). As previously set forth, Mujtaba and colleagues provide acetylated HIV-1 Tat peptides. These peptides were acetylated at Lys^{50} and comprise the core sequence SYGRKKRRQ. This teaching does not disclose acetylated Tat peptides that contain a C-terminal cysteine residue. However, Wildey and associates unequivocally demonstrate that attaching a C-terminal cysteine residue to a polypeptide facilitates its conjugation to a carrier protein. Therefore, it would have been *prima facie*

obvious to one of ordinary skill in the art at the time of the invention to modify the polypeptides of Mujtaba et al. (2002), to include a C-terminal cysteine residue, as taught by Wildey et al. (1988), since this would facilitate the conjugation of these peptides to a carrier protein. It would have also been *prima facie* obvious to use Ac-Tat polypeptides (SYGRKKRRQRC, SYGRKKRRQRRC, and SYGRKKRRQRRRC) up to and including the end of the basic domain (aa 57) as targets for antibody generation since this is a hydrophilic region and it has been well-demonstrated that hydrophilicity correlates to immunogenicity.

Claims 6-18 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Mujtaba *et al.* (2002) in view of Wildey *et al.* (1988) and Gu *et al.* (2002). The claims contain additional art-recognized limitations pertaining to the nature of the immunogenic composition (i.e., presence of a linker, carrier protein, adjuvant, etc.). The teachings of Mujtaba *et al.* (2002) and Wildey *et al.* (1988) have already been set forth. Gu and colleagues provide immunogenic compositions comprising polypeptides linked to a carrier (e.g., tetanus toxoid) through a linker containing an adjuvant (e.g., ALUM) (see claims). Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to prepare immunogenic compositions, as taught by Gu *et al.* (2002), comprising the Ac-Tat polypeptides of Mujtaba *et al.* (2002) and Wildey *et al.* (1988), since this would reasonably be expected to generate strong immune responses against Ac-Tat.

Correspondence

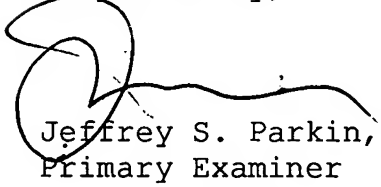
Any inquiry concerning this communication should be directed to Jeffrey S. Parkin, Ph.D., whose telephone number is (571)

272-0908. The examiner can normally be reached Monday through Thursday from 10:30 AM to 9:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Bruce R. Campell, Ph.D., can be reached at (571) 272-0974. Direct general status inquiries to the Technology Center 1600 receptionist at (571) 272-1600. Informal communications may be submitted to the Examiner's RightFAX account at (571) 273-0908.

Applicants are reminded that the United States Patent and Trademark Office (Office) requires most patent related correspondence to be: a) faxed to the Central FAX number (571-273-8300) (updated as of July 15, 2005), b) hand carried or delivered to the Customer Service Window (now located at the Randolph Building, 401 Dulany Street, Alexandria, VA 22314), c) mailed to the mailing address set forth in 37 C.F.R. § 1.1 (e.g., P.O. Box 1450, Alexandria, VA 22313-1450), or d) transmitted to the Office using the Office's Electronic Filing System. This notice replaces all prior Office notices specifying a specific fax number or hand carry address for certain patent related correspondence. For further information refer to the Updated Notice of Centralized Delivery and Facsimile Transmission Policy for Patent Related Correspondence, and Exceptions Thereto, 1292 Off. Gaz. Pat. Office 186 (March 29, 2005).

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,



Jeffrey S. Parkin, Ph.D.
Primary Examiner
Art Unit 1648

16 April, 2007